NEUROLOGICAL SURGEONS, P.C.

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December 6, 1999

Document Management Branch (HPA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: DOCKET #97N-484S

Sirs:

I strongly oppose the FDA regulation regarding regulating allograft tissue published in the September 30, 1999 issue of a Federal Register. Neurosurgeon and orthopedic surgeons use banked bone and other tissues for treatment of our patients. The proposed regulation could lead to significant reduction in the supply of these products with significant adverse effects for patients who are in need of same. I urge the FDA to not implement this regulation.

Please feel free to contact me at any time if you desire further comment or amplification of the above.

Sincerely yours,

Lewis J. Brown M.D./sa

PHOENIX

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